INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR CONTINUATION APPROVAL OF PROTOCOL

Date Rec'd in HSO _____

Instructions: Use this form when submitting protocols for continuing review. Review is required AT LEAST annually; however, the IRB may have determined that your protocol will need to be reviewed more often. Please submit this form electronically along with the current consent form and a copy of the protocol (if changed since last year) and any supporting documents (if changed since last year) to the CIO designated staff official. However, if submitted in hardcopy, please send the original and three copies all documents to the CIO designated official. Consecutively number **ALL** pages, beginning with the title page of the protocol (if applicable), followed by any consent form(s) and any applicable ancillary documents. Complete all applicable items or the form will be returned.

Date Submitted by Investigator: _____

PROTOCOL NO. _____

Title of Protocol: _____

Proposed Dates for Project - Begin: _____ End: _____

Name of CDC Employee Serving as Principal Investigator (PI) and Degrees:

_____

9 Check if PI has changed

Scientific Ethics Verification No.: _____ Telephone: _____ Fax: _____

CIO: _____ **Division:** _____ **MS:** _____ Email Address: _____

Names of Other CDC Employee Co-investigators (use supplemental page if > than 3):

1. _____ *Scientific Ethics* Verification No.: _____

2. _____ *Scientific Ethics* Verification No.: _____

3. _____ *Scientific Ethics* Verification No.: _____

1. Current Status

_____ Study not yet begun (Provide explanation in item 4. Complete item 6, if applicable)

_____ Active research; contact with subjects continuing (Complete items 2-9)

_____ Active research with subjects completed; study activities involve only data analysis and/or report writing (Complete items 2,5,6,7,8 & 10)

_____ Study does not involve contact with subjects (e.g., research using existing records); study activities involve only data analysis and/or report writing (Complete items 5,6,7,10)

2. Study Population (If an international study, provide race/ethnicity of subjects by percentages:

_____

_____ Enrolled this past year

_____ Total number of subjects to date

_____ Declined enrollment this past year

_____ Withdrawn from project this past year

For individuals who were enrolled this year:

Gender distribution:
_____ % Female _____ % Male

Race/ethnicity distribution of enrolled subjects for domestic studies:

_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander
_____ % Black or African American, not of Hispanic origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

Vulnerable Populations Have any of these populations been added to the study? _____ YES _____ NO
(If **YES**, please check all that apply):

_____ Pregnant women (as a SPECIFIC target group)
_____ Fetuses (Ref: 45CFR46, Subpart B)
_____ Prisoners (Ref: 45CFR46, Subpart C)
_____ Children 17 years of age or younger (Ref: 45CFR46, Subpart D)
_____ Mentally disabled
_____ Educationally or economically disadvantaged

3. Collaborating Sites (Use additional sheets if necessary)**:**

3a. List any collaborating sites by name and location (including state) that were added since last continuation approval:

_____ None added

	OPRR Assurance No.:
1.	
2.	
3.	
4.	
5.	

3b. List any collaborating sites by name and location (including state) that were deleted since last continuation approval:

_____ None deleted

1.
2.
3.
4.
5.

4. FUNDING (check one):

_____ PGO Funding Mechanism Used:

_____ Cooperative Agreement No(s).: _____

_____ Contract No(s).: _____

_____ Grant: _____

_____ Purchase Order (a.k.a. Simplified Acquisition):

_____ Other funding mechanism:

_____ Memorandum of Understanding (MOU) (With whom): _____

_____ Interagency Agreement (IAA) (Name of other agency): _____

_____ Other (Specify type and with whom): _____

_____ Only CDC investigators performing study

_____ Collaborative (Non-CDC investigators & CDC investigators; no funding involved)

5. Summary of Activities to Date (Use additional sheets as necessary):

6. Summary of Study Modifications Reviewed and Approved This Past Year (Use additional sheets as necessary):

_____ None

7. Summary of Any New Literature, Findings, or Other Relevant Information (Use addition sheets as necessary):

_____ None

8. **Summary of Adverse Events or Unanticipated Problems** (Use additional sheets as necessary):

_____ None

9. Consent Documents (Attach a copy of each current consent form, telephone consent text, and/or consent letter):

10. Summary of Remaining Activities (Use additional sheets as necessary):

Approvals (Signature and Position Title): Branch Chief:	**Date:**	**Remarks:**
Division Director:		
CIO Human Subjects Contact:		